

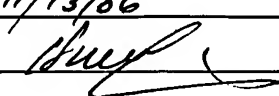
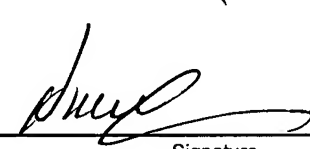
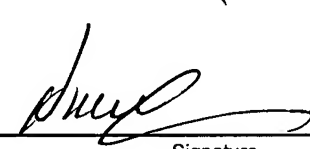
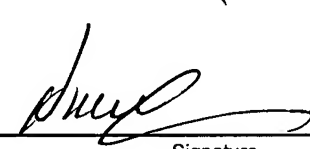


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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) HAN-031/DEP5692USNP									
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		First Named Inventor Jorge L. Orbay									
		Art Unit 3733	Examiner Richard R. Shaffer								
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table border="0"><tr><td><input type="checkbox"/> applicant/inventor.</td><td><u></u> Signature</td></tr><tr><td><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</td><td><u>David S. Jacobson</u> Typed or printed name</td></tr><tr><td><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>39,235</u></td><td><u>203-323-1800</u> Telephone number</td></tr><tr><td><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</td><td><u>11/13/06</u> Date</td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>				<input type="checkbox"/> applicant/inventor.	<u></u> Signature	<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	<u>David S. Jacobson</u> Typed or printed name	<input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>39,235</u>	<u>203-323-1800</u> Telephone number	<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____	<u>11/13/06</u> Date
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<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	<u>David S. Jacobson</u> Typed or printed name										
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☒ *Total of 1 forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 10/806,540

Group Art Unit: 3733

Filed: March 23, 2004

Examiner: Richard R. Shaffer

Applicant: Jorge L. Orbay et al.

Attorney Docket: HAN-031

DePuy Docket: DEP5692USNP

Title: Cap for Cut Metal Orthopedic Fastener

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David S. Jacobson

Date

Honorable Commissioner for Patents
Alexandria, VA 22313

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW ARGUMENTS

For purposes of the following, the claims stand as amended by the applicant's Reply dated May 25, 2006.

Claim 27 stands improperly rejected under 35 U.S.C. § 112, first paragraph

The Examiner is improperly maintaining a rejection of claim 27 on the basis that applicant is "omitting the values between 5.11 and 6 for ratio comparisons." See Advisory Action dated Oct. 18, 2006, Continuation of 3, lines 3-4. Applicant does not omit or disclaim any value in the stated range. Applicant claims a larger range of "at least approximately five times" (claim 1), and a narrower range of "at least six times" (claim 27). Therefore, the basis of the Examiner's rejection is clearly improper for

reasons previously set forth in detail in applicant's reply of October 11, 2006 at pages 9-10.

Claims 1, 2, 4-7, 12-15, 19-20 and 28 stand improperly rejected under 35 U.S.C.

§ 102(b) by Simmons

The Examiner has failed to establish a prima facie rejection of the claims rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 5,894,110 to Simmons et al. (Simmons) for the following reasons. In order to support a rejection of a claim under 35 U.S.C. § 102(b), "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Claim 1 requires a radiopaque composition and claim 12 requires a radiopaque plastic material. Simmons discloses a wire nut manufactured from a plastic that is not radiopaque. The Examiner states that in view of the disclosure in the Specification he is interpreting the claimed radiopaque structure "as being any plastic capable of being combined with a radiopaque material." The cited reference does not teach all the elements of the claimed invention in as complete detail as contained in the claim. Therefore, the Examiner has not established a prima facie rejection of the claims. Detailed arguments relating to the above are provided in applicant's reply of October 11, 2006 at pages 11-12.

Furthermore, with respect to claim 5, the "lead-in portion" (identified by the Examiner between the open end and reference numeral 16; see Office Action of August 11, 2006 at bottom page 3 – top of page 4) is not cylindrical as required by the claim.

Also, with respect to claim 6, it is also required that the engagement portion be cylindrical. The Examiner does not define the portion of Simmons which he believes corresponds to the “engagement portion”, but assuming it is from the “lead-in portion” forward, it is noted that such portion also tapers in Simmons. See complete arguments in Applicant’s reply of October 11, 2006 at page 12. Therefore, elements pertaining to specific claims are also omitted from the reference, preventing the establishment of a prima facie rejection.

Claims 21-24 and 29 stand improperly rejected under 35 U.S.C. § 102(b) by
Finlayson

The Examiner has failed to establish a prima facie rejection of the claims rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 5,885,227 to Finlayson for the following reasons.

Claim 21 requires a combination of a metal orthopedic nail and a cap. The Finlayson reference does not teach such nail sufficiently to anticipate the element. The Examiner is taking an unreasonably broad interpretation of “metal orthopedic nail”: “A relatively elongated and straight member that can be inserted into a member.” It is inherent in the nature, substance, and structure of an orthopedic nail that it be capable of supporting a bone across a fracture. The Examiner indicates that an orthopedic nail is disclosed in the guidewire reference of Finlayson at element 12d at the very end of the core 12 of guidewire 10. (See Office Action of August 11, 2006, page 7, top paragraph) The Examiner limits his arguments to the distal end element 12d ostensibly for

consistency in applying the reference to other limitations of the claims. However, element 12d is a flattened ultraflexible distal end portion 12d of the core of the flexible guidewire, having a length of approximately 1.5 cm. Regardless of whether the bendable flattened tip of a guidewire can be fed through the marrow of the medullary canal of a bone, it does not have the structure to support a bone across a fracture. See complete arguments in Applicant's reply dated October 11, pages 13-17.

The claimed combination also requires that a lead-in portion of the cap be spaced apart from the end of the nail by a "clearance". In Finlayson, the cap 20 of the guidewire 10 is in direct contact with the core 12 of the guidewire 10 along its entire length, and particularly along portion 12d thereof. Thus, element 12d may be distanced from the entry of the cap, but there is *no clearance*; i.e., a space thereabout—there is always plastic in direct contact with the end of the core along its entire length. See complete arguments in applicant's Reply dated October 11, pages 13-14.

Furthermore, with respect to claim 22, the claimed nail is required to have a "non-passivated *cut end*". As set forth in the Specification (pages 1-2), small diameter orthopedic nails, e.g., K-wires, are often inserted into bones. Such nails are "passivated" to increase corrosion resistance and reduce reactivity in the human body. Finlayson provides no teaching or suggestion with respect to whether the end thereof is passivated or non-passivated. See applicant's detailed arguments in Reply dated October 11, 2006 at page 15.

Further, in the Examiner's Response to Arguments (Office Action of August 11, 2006, page 7, second paragraph), the Examiner states that one cannot determine whether nail 12d was passivated prior to placing cap 20, but concludes that the cap now is what passivates the "nail" 12d. Regardless, the claim requires that the end of the nail under the cap be non-passivated and cut. Again, Finlayson provides no teaching required to anticipate this limitation.

Conclusion

In light of all of the above, it is submitted that the Examiner has not made a prima facie rejection of the claims. A favorable opinion from the panel is respectfully requested so that the case may proceed expeditiously to allowance.

Respectfully submitted,



David S. Jacobson
Reg. No. 39,235
Attorney for Applicant(s)

GORDON & JACOBSON, P.C.
60 Long Ridge Road
Suite 407
Stamford, CT 06902
Ph: 203-323-1800
Fax: 203-323-1803

November 11, 2006